IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
Civil Action No. 5:20-cv-536-FL

BECTON, DICKINSON AND COMPANY, Plaintiff, vs. BIOMEDOMICS, INC. Defendant.	**PLAINTIFF'S VERIFIED ANSWER AND RESPONSE TO AMENDED COUNTERCLAIM**

Plaintiff Becton, Dickinson and Company ("BD") provides its Answer and Response to Defendant BioMedomics, Inc.'s ("BioMedomics") Amended Counterclaim in this action and shows the Court the following:

PRELIMINARY STATEMENT

1. On March 10, 2020, BioMedomics submitted a pre-Emergency Use Authorization ("pre-EUA") for the COVID-19 IgM/IgG assay (the "Product") to the Food and Drug Administration ("FDA"). A pre-EUA package contains data and information about the safety, quality, and efficacy of the product, its intended use under a future or current EUA, and information about the emergency or potential emergency situation.

2. On or about March 14, 2020, a BD representative initiated contact with Frank Wang ("Mr. Wang"), a resident of North Carolina and CEO of BioMedomics, a North Carolina corporation, to learn about the Product.

3. On March 16, 2020, the FDA released a policy on serology tests for the SARS-CoV-2 infection that would permit the distribution and use of a serology test when it had been validated, notification was provided to the FDA, and warning statements were included with the test.

4. On March 19, 2020, pursuant to this policy, BioMedomics notified the FDA of its Product, which was considered a serology test.

5. On March 23, 2020, a BD representative conducted a diligence visit at BioMedomics's manufacturing facility in North Carolina.

6. On March 25, 2020, the parties discussed the logistics of a term sheet for the exclusive purchase and delivery of the Product for distribution in the United States. In an email exchange, Mr. Wang informed Troy Hopps ("Mr. Hopps") of BD that BioMedomics would attempt to reach a schedule of delivery of 600,000 units (first week), 1,000,000 units (second week), 2,000,000 units (third week), and 3,300,000 units (fourth week). Mr. Wang also informed Mr. Hopps that BioMedomics had current pending orders of the Product with other customers to satisfy.

7. On March 26, 2020, BD and BioMedomics entered into a Term Sheet for Exclusive Distribution Agreement (the "Term Sheet").

8. On March 29, 2020, BD issued a purchase order for 1,000,000 units of the Product to be distributed in the United States. BioMedomics generated an invoice for the purchase order.

9. On April 1, 2020, the FDA provided feedback and questions to BioMedomics regarding the pre-EUA submitted for the Product.

10. On April 1, 2020, Cheryl Fried ("Ms. Fried"), Associate General Counsel for BD, sent a first draft of a distribution agreement to Dan O'Korn ("Mr. O'Korn"), outside counsel for BioMedomics.

11. On April 7, 2020, Mr. Hopps emailed Mr. Wang, and among other things, raised questions regarding the manufacturing capacity of BioMedomics to meet previously discussed estimates of the units of Product that BioMedomics represented it could deliver. Mr. Hopps stated: "It is critical that we align on the above points with a solid path forward to ensure we are able to meet the significant demand for both the US market as well as opportunities outside the US."

12. On April 9, 2020, BD picked up 50,000 tests from BioMedomics's facility in North Carolina.

13. On April 14, 2020, BioMedomics submitted pre-EUA Amendment 1 to the FDA in response to the FDA's April 1 correspondence.

14. On April 16, 2020, BD issued a second purchase order for 500,000 units of the Product to be distributed in the United States. BioMedomics generated an invoice for the purchase order.

15. On April 18, 2020, Brad Heidinger ("Mr. Heidinger"), of BioMedomics notified Jean-Francois Mathieu ("Mr. Mathieu") of BD that BioMedomics intended to use Stephen Gould

Corporation, a company with a facility in North Carolina, to assist with the "kitting" of the Product in North Carolina.

16. On April 20, 2020, Mr. Hopps and Mr. Wang had a call to discuss BD's proposal for distribution of the Product outside of the United States. Mr. Hopps emailed a list of items BD would like incorporated into an additional term sheet, including BD purchasing a minimum of 1,500,000 units for the next twelve months, and a proposed price of $5.00/test for distribution outside of the United States.

17. On April 22, 2020, Mr. Wang responded to Mr. Hopps's April 20 email, indicating that the parties needed to agree on price. He proposed a price of $8.00/test for distribution outside of the United States. He noted that he also spoke with BioMedomics's lawyer regarding the next steps.

18. On April 23, 2020, BD picked up 50,000 additional tests from BioMedomics's facility in North Carolina.

19. On April 23, 2020, Mr. O'Korn returned a draft of the distribution agreement to BD with comments, noting in his cover email his understanding that territory and pricing was still being discussed by Mr. Wang and "business folks" at BD.

20. On April 24, 2020, BioMedomics received a second set of questions regarding the pre-EUA from the FDA.

21. On April 25, 2020, BioMedomics submitted pre-EUA Amendment 2.

22. On April 26, 2020, BD sent another draft of the distribution agreement to BioMedomics.

23. On April 27, 2020, Mr. Hopps emailed Mr. Wang and proposed a price of $6.00/test for distribution outside of the United States.

24. On April 27, 2020, Mr. Mathieu of BD requested that BioMedomics provide updates on best estimates for BioMedomics to be able to deliver the Product in May and June.

25. On April 28, 2020, Mr. Heidinger of BioMedomics emailed Mr. Mathieu of BD representing that BioMedomics would need to complete deliveries of the Product in May (1,500,000 units) and June (2,000,000 units), and stated: "Hopefully we will get some good news on the EUA and this will give us some assurance that shipments will begin to move more freely."

26. On April 29, 2020, Mr. Wang emailed Mr. Hopps stating he was working with his side for a price of $6.50/test for distribution outside of the United States for the Product, but was getting resistance from BioMedomics's board members.

27. On April 30, 2020, Mr. Mathieu of BD emailed Mr. Heidinger of BioMedomics in an effort to obtain the most accurate shipping schedule for the Product from BioMedomics, suggesting 1,500,000 units in April for distribution in the United States, 1,000,000 units in May for distribution in the United States as well as 1,000,000 units in May for distribution outside of the United States, and 2,000,000 units per month for June through September for distribution in the United States as well as 1,500,000 units per month for June through September for distribution outside of the United States. Mr. Mathieu noted discussions were ongoing between Mr. Hopps and Mr. Wang.

28. On April 30, 2020, Mr. Heidinger responded to Mr. Mathieu regarding potential shipments from BioMedomics. Mr. Heidinger stated there were "still lots of uncertainties and things remain[ed] a bit in flux" and proposed a different pick up schedule. He also stated that he did not want to commit to set deliverables until there was a signed contract for distribution outside of the United States.

29. On May 4, 2020, Ms. Fried of BD emailed another version of the distribution agreement to Mr. O'Korn noting revisions to additional territories and pricing.

30. On May 4, 2020, the FDA modified its policy on serology testing, noting that their March 16 policy had succeeded in encouraging the development of serology tests. The new guidance allowed manufacturers to distribute serology tests after validation, for a limited period of time, while an EUA was being prepared for submission to the FDA.

31. On May 6, 2020, BioMedomics notified the FDA of its intent to withdraw the pre-EUA, suspend distribution of the current test, and validate a next generation ("Gen2") Product to submit a new EUA.

32. On May 26, 2020, Mr. Hopps emailed Mr. Wang to follow up on an earlier same-day discussion. He confirmed that BioMedomics would ship to the United States the remaining 1,400,000 units under existing purchase orders for United States distribution. He set forth a schedule that BioMedomics would provide 1,000,000 tests for distribution outside of the United States in June and 1,500,000 tests per month for distribution outside of the United States from July through September, and stated that BD would issue purchase orders for those orders. Mr. Wang responded on the same day, saying that "We will finalize this on a formal agreement."

33. On May 27, 2020, BioMedomics submitted a new EUA for Gen2 of the Product to the FDA.

34. On May 27 and 28, 2020, Mr. Mathieu emailed Mr. Wang and Mr. Heidinger of BioMedomics with "an objective to get a clear picture" of BioMedomics's ability to deliver the remaining 1,400,000 units of the Product under the existing purchase orders by June, and BioMedomics's ability to deliver subsequent units of the Product for distribution both in the United States and outside the United States.

35. On May 29, 2020, Mr. Hopps and Mr. Wang had another call to discuss the terms of the distribution agreement, including volumes.

36. On May 31, 2020, Mr. Mathieu again emailed Mr. Wang and Mr. Heidinger of BioMedomics regarding BioMedomics's ability to deliver subsequent units of the Product for the United States, including the outstanding 1,400,000 units under the existing purchase orders, as well as Product for distribution outside of the United States.

37. On June 2, 2020, Mr. Heidinger stated in emails to Mr. Mathieu that "We need to be careful that BD's efforts don't interfere with BioMedomics' sales opportunities that we have been nurturing," and "BioMedomics has already built some very good opportunities in a few of these countries and we need to make sure both of our teams are in alignment."

38. On June 6, 2020, Mr. Hopps and Mr. Wang had another call to discuss the terms of the distribution agreement.

39. On June 7, 2020, in an email to Mr. Wang, Mr. Hopps stated the parties had discussed having one price for the product worldwide. BD proposed a price of $5.25/test for

worldwide distribution. He noted: "BD looks forward to the EUA approval so that the parties may move forward."

40. On June 8, 2020, Mr. Wang emailed Mr. Hopps and stated that $5.25/test was too low and that BioMedomics wanted to discuss pricing more.

41. On June 11, 2020, BioMedomics issued a recall notice for any Product distributed in the United States pursuant to its notification to the FDA that it would suspend distribution of the first generation of the Product.

42. On June 14, 2020, BioMedomics submitted Amendment 1 to the pending EUA to provide updated serology template information.

43. On June 15, 2020, BD sent another revised version of the distribution agreement.

44. On June 17, 2020, BioMedomics sent another revised version of the distribution agreement.

45. On June 24, 2020, BD sent another revised version of the distribution agreement.

46. On June 25, 2020, BioMedomics responded regarding the most recent draft of the distribution agreement following a call that same day. Mr. O'Korn specifically addressed in his cover email Section 16.5 of the draft distribution agreement that provided that BD could cancel the distribution agreement if the FDA did not grant or revoked an EUA for the Product. Mr. O'Korn stated that BioMedomics would keep Section 16.5 in the Distribution Agreement, but wanted BD to have the termination right after 60 days, rather than 30.

47. On July 7, 2020, BioMedomics followed up with the FDA regarding the pending EUA.

48. On July 7, 2020, BioMedomics and BD had another call to discuss pricing for the distribution agreement.

49. On July 9, 2020, the FDA notified BioMedomics about concerns it had regarding the EUA submission.

50. On July 10, 2020, BioMedomics responded to the FDA.

51. On July 28, 2020, the FDA sent BioMedomics results of the serology testing for the Gen2 Product, noting significant performance concerns with the Product that indicated the Product was not validated for intended use.

52. On August 11, 2020, BioMedomics had a call with the FDA wherein the FDA stated that a new set of validation data would be necessary, thus requiring that a third generation of the Product be developed and a new separate EUA for the third generation of the Product be submitted.

53. Following the call with the FDA on August 11, the parties knew that there was no path forward for the Gen2 Product to receive an EUA.

54. On August 12, 2020, BioMedomics notified the FDA that it was withdrawing the current EUA and planned to submit a new one.

55. On August 14, 2020, BD sent a termination notice regarding the two previously issued purchase orders.

ANSWER TO COUNTERCLAIM

Each and every allegation of the Answer and Counterclaim is expressly denied unless specifically admitted, qualified, or explained herein.

JURISDICTION AND VENUE

1. BD admits the allegations of this paragraph.

2. BD admits the allegations of this paragraph.

3. The allegations of this paragraph constitute legal conclusions to which a response is not required. To the extent that further response is required, BD denies the allegations of this paragraph.

FACTS

4. BD admits that it is a corporation existing by virtue of the laws of the State of New Jersey that has its principal place of business at One Becton Drive, Franklin Lakes, New Jersey 07417. BD further admits that it sells medical devices, instrument systems, and reagents. Except as expressly admitted, BD denies the remainder of this paragraph as written.

5. BD lacks knowledge and information sufficient to form a reasonable belief as to the truth of the allegations of this paragraph. To the extent that further response is required, the allegations are denied.

6. BD lacks knowledge and information sufficient to form a reasonable belief as to the truth of the allegations of this paragraph. To the extent that further response is required, the allegations are denied.

7. BD admits the allegations of this paragraph.

8. BD admits the allegations of this paragraph.

9. BD lacks knowledge and information sufficient to form a reasonable belief as to the truth of the allegations of this paragraph. To the extent that further response is required, the allegations are denied.

10. BD admits the allegations of this paragraph.

11. BD admits the allegations of this paragraph.

12. BD admits the allegations of this paragraph.

13. The referenced document speaks for itself as a matter of fact and law, and therefore no response is required. BD denies any allegation of this paragraph inconsistent therewith.

14. BD admits only that on April 2, 2020, Mr. Wang, Mr. Hopps, and Dave Hickey of BD met via conference call. Except as expressly admitted, BD denies the allegations of this paragraph.

15. BD denies the allegations of this paragraph. The referenced Exhibit A speaks for itself as a matter of fact and law, and therefore no response to that portion of the paragraph is required. BD denies any allegation of this paragraph inconsistent therewith.

16. The referenced Exhibit B speaks for itself as a matter of fact and law, and therefore no response to that portion of the paragraph is required. BD denies any allegation of this paragraph inconsistent therewith.

17. BD admits that on April 28, 2020, further discussions occurred between the parties regarding a potential distribution schedule of the Product. Except as expressly admitted,

BD denies the remainder of this paragraph as written, and refers to Paragraphs 23-28 of the Preliminary Statement.

18. The referenced Exhibit B speaks for itself as a matter of fact and law, and therefore no response is required. BD denies any allegation of this paragraph inconsistent therewith.

19. The referenced Exhibit C speaks for itself as a matter of fact and law, and therefore no response is required. BD denies any allegation of this paragraph inconsistent therewith.

20. BD admits the allegations of this paragraph.

21. BD admits the allegations of this paragraph.

22. BD admits, upon information and belief, that BioMedomics internally tested Gen2 of the Product and BD reviewed Gen2 of the Product. Except as expressly admitted, BioMedomics denies the allegations of this paragraph.

23. BD lacks knowledge and information sufficient to form a reasonable belief as to the truth of the allegations of this paragraph. To the extent that further response is required, the allegations are denied.

24. The referenced Exhibit D speaks for itself as a matter of fact and law, and therefore no response to that portion of the paragraph is required. BD denies any allegation of this paragraph inconsistent therewith.

25. BD admits that the parties continued discussions regarding the production and shipment of tests by BioMedomics. Except as expressly admitted, BD denies the allegations of this paragraph and refers to Paragraphs 32-36 of the Preliminary Statement.

26. The referenced Exhibit D speaks for itself as a matter of fact and law, and therefore no response is required. BD denies any allegation of this paragraph inconsistent therewith.

27. The referenced Exhibit D speaks for itself as a matter of fact and law, and therefore no response is required. BD denies any allegation of this paragraph inconsistent therewith.

28. BD denies the allegations of this paragraph.

29. The referenced Exhibit D speaks for itself as a matter of fact and law, and therefore no response is required. BD denies any allegation of this paragraph inconsistent therewith.

30. BD admits the allegations of this paragraph.

31. BD denies the allegations of this paragraph and refers to Paragraphs 32-36 of the Preliminary Statement.

32. BD denies the allegations of this paragraph and refers to Paragraphs 32-36 of the Preliminary Statement.

33. BD admits that the parties discussed transportation and materials costs for the Product. Except as expressly admitted, BD denies the allegations of this paragraph.

34. BD admits that on May 29, 2020, Mr. Hopps and Mr. Wang had another call to discuss the terms of a proposed distribution agreement. BD further admits that on June 5, 2020, the parties engaged in email correspondence regarding a proposed shipment of the Product to the European Union. Except as expressly admitted, BD denies the allegations of this paragraph.

35. BD lacks knowledge and information sufficient to form a reasonable belief as to the truth of the allegations of this paragraph. To the extent that further response is required, the allegations are denied. The referenced Exhibit E speaks for itself as a matter of fact and law, and therefore no response to that portion of the paragraph is required. BD denies any allegation of this paragraph inconsistent therewith.

36. BD denies the allegations of this paragraph.

37. BD denies the allegations of this paragraph and expressly denies that any agreement ever existed between the parties for distribution outside of the United States.

38. BD admits only that on August 14, BD sent a termination notice regarding the two previously issued purchase orders. Otherwise, the referenced document speaks for itself as a matter of fact and law, and therefore no response is required. BD denies any allegation of this paragraph inconsistent therewith and further denies that any agreement ever existed between the parties for distribution outside of the United States.

39. BD lacks knowledge and information sufficient to form a reasonable belief as to the truth of the allegations of this paragraph. To the extent that further response is required, the allegations are denied.

40. BD denies the allegations of this paragraph.

41. BD denies the allegations of this paragraph.

42. BD denies the allegations of this paragraph.

FIRST CAUSE OF ACTION
(BREACH OF CONTRACT)

43. BD hereby realleges its responses to paragraphs 1 through 42 above as if fully set forth herein.

44. The allegations of this paragraph constitute legal conclusions to which a response is not required. To the extent that further response is required, BD admits the allegations of this paragraph.

45. BD denies the allegations of this paragraph.

46. BD denies the allegations of this paragraph.

47. BD denies the allegations of this paragraph.

48. BD denies the allegations of this paragraph.

49. BD denies the allegations of this paragraph.

50. BD denies the allegations of this paragraph.

51. BD denies the allegations of this paragraph.

52. BD denies the allegations of this paragraph.

SECOND CAUSE OF ACTION
(PROMISSORY ESTOPPEL)

53. BD hereby realleges its response to paragraph 1 through 52 above as if fully set forth herein.

54. BD denies the allegations of this paragraph.

55. BD denies the allegations of this paragraph.

56. BD denies the allegations of this paragraph.

57. BD denies the allegations of this paragraph.

FIRST AFFIRMATIVE DEFENSE

BioMedomics fails to state a claim against BD upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

BioMedomics's claim of breach of contract (the existence of which BD denies) is barred by the statute of frauds.

THIRD AFFIRMATIVE DEFENSE

BioMedomics failed to mitigate its damages.

FOURTH AFFIRMATIVE DEFENSE

BioMedomics's breach of contract claim (the existence of which BD denies) is barred by the failure of performance and the failure of consideration.

FIFTH AFFIRMATIVE DEFENSE

BioMedomics's claims are barred, in whole or in part, by the doctrine of unclean hands.

SIXTH AFFIRMATIVE DEFENSE

BioMedomics's claims are barred, in whole or in part, by the doctrine of laches, estoppel, or waiver.

SEVENTH AFFIRMATIVE DEFENSE

BioMedomics's claims are barred, in whole or in part, by the doctrine of consent or acquiescence.

EIGHTH AFFIRMATIVE DEFENSE

BioMedomics's claims are contrary to custom and practice in the industry.

NINTH AFFIRMATIVE DEFENSE

Any damages allegedly sustained by BioMedomics, which are denied, were caused only by the acts or omissions of entities or persons other than BD, which acts or omissions constitute the intervening and superseding cause of the BioMedomics's alleged damages and bar the claims against BD.

TENTH AFFIRMATIVE DEFENSE

BioMedomics's injuries or damages, if any, were the result of intervening or superseding events, factors, occurrences, or conditions, which were in no way caused by BD and for which BD is not liable.

RESERVATION OF ADDITIONAL DEFENSES

Defendant reserves the right to amend this Verified Answer and Response to First Amended Counterclaim to assert such additional defenses as may become apparent through discovery or otherwise.

WHEREFORE, Plaintiff Becton, Dickinson and Company respectfully prays the Court as follows:

1. That the Defendant have and recover nothing from BD by way of the Counterclaims;

2. That the costs of this action, including reasonable attorney's fees, be taxed against the Defendant to the extent permitted by applicable law;

3. For a trial by jury on all issues; and

4. For such other and further relief as the Court deems just and equitable.

This the 28th day of December 2021.

NELSON MULLINS RILEY & SCARBOROUGH LLP

/s/ Chelsea K. Barnes
Mark A. Stafford, NC Bar No. 16835
Chelsea K. Barnes, NC Bar No. 53378
Nelson Mullins Riley & Scarborough LLP
380 Knollwood Street, Suite 530
Winston-Salem, NC 27103
Phone: 336.774.3333 / Fax: 336.774.3376
Email: mark.stafford@nelsonmullins.com
chelsea.barnes@nelsonmullins.com

James F. Rogers, *pro hac vice*
Adam J. Hegler, *pro hac vice*
Nelson Mullins Riley & Scarborough LLP
1320 Main Street, 17th Floor
Columbia, SC 29201
Phone: 803.255.9489
E-mail: jim.rogers@nelsonmullins.com
adam.hegler@nelsonmullins.com
Counsel for Plaintiff/Counterclaim Defendant

CERTIFICATE OF SERVICE

I hereby certify that on December 28, 2021 I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to the following counsel of record for Defendant:

Walter L. Tippett Jr.
William A. Robertson
1700 Wells Fargo Capitol Center
150 Fayetteville Street
Raleigh, NC 27601
Email: wtippett@brookspierce.com
wrobertson@brookspierce.com

Counsel for Defendant/Counterclaim Plaintiff

/s/ Chelsea K. Barnes
Chelsea K. Barnes

VERIFICATION

Jean-Francois Mathieu, as Senior Director, TTM Platform Leader of Becton, Dickinson and Company, deposes and says that he has read the contents of the foregoing Answer and Response to Amended Counterclaim, knows the contents thereof, and that the same are true of his own knowledge, except as to matters stated upon information and belief, and as to those matters, he believes them to be true.

I verify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this the __21__ day of December 2021.

BECTON, DICKINSON AND COMPANY

By: 

_____

Jean-Francois Mathieu
Senior Director, TTM Platform Leader